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(71) Applicant(s)
Gyrus Medical Limited
(Incorporated in the United Kingdom)
Fortran Road, St Mellons, CARDIFF, CF3 OLT,
United Kingdom

(72) Inventor(s)
Nigel Mark Goble
Colin Charles Owen Goble

(74) Agent and/or Address for Service
Withers & Rogers
4 Dyer's Buildings, Holborn, LONDON, EC1N 2JT,
United Kingdom

(54) Abstract Title
Electrosurgical instrument

(57) An electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium comprises an instrument shaft 10, and an active side-effect tissue treatment electrode 12 at the distal end of a tungsten rod 14 within the shaft 10 for electrosurgically excising tissue pieces at an operation site. A ceramic tip 20 has an aperture 20a through which matter can be aspirated and removed from the region surrounding the electrode 12 by way of a channel formed within the shaft 10 and leading from the aperture 20a to a suction port 10a. The tissue treatment electrode 12 is coupled to a motor 44 so as to move cyclically relative to the shaft 10, ad causes electrosurgical morcellation of the tissue pieces. Build-up of sublimation products or other material in the channel is prevented by the movement of rod 14, causing agitation. An RF power source is coupled to connectors 46,48. The rod 14 may be flexible, offset or cranked, and may be rotated. The electrode 12 may be end-effect.

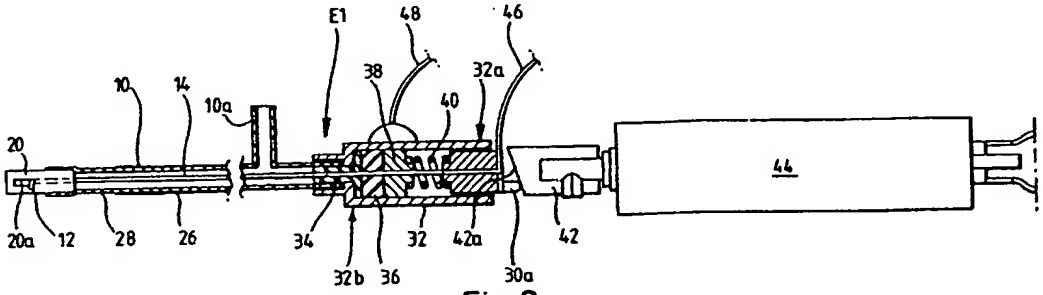

Fig.2.

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The Patent Office

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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

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Other: Online: EDOC, JAPIO, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2179861 A	(KHARKOVSKY)	-
A	EP 0509670 A2	(EVEREST)	-
A	US 5591141	(NETTEKOVEN)	-

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

AN ELECTROSURGICAL INSTRUMENT

This invention relates to an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, to electrosurgical apparatus including such an instrument, and to an electrode unit for use in such an instrument. Endoscopic electrosurgery is useful for treating tissue in cavities of the body, and is normally performed in the presence of a distension medium. When the distension medium is a liquid, this is commonly referred to as underwater electrosurgery, this term denoting electrosurgery in which living tissue is treated using an electrosurgical instrument with a treatment electrode or electrodes immersed in liquid at the operation site. A gaseous medium is commonly employed when endoscopic surgery is performed in a distensible body cavity of larger potential volume in which a liquid medium would be unsuitable, as is often the case in laparoscopic or gastroenterological surgery.

Underwater surgery is commonly performed using endoscopic techniques, in which the endoscope itself may provide a conduit (commonly referred to as a working channel) for the passage of an electrode. Alternatively, the endoscope may be specifically adapted (as in a resectoscope) to include means for mounting an electrode, or the electrode may be introduced into a body cavity via a separate access means at an angle with respect to the endoscope - a technique commonly referred to as triangulation. These variations in technique can be subdivided by surgical speciality, where one or other of the techniques has particular advantages given the access route to the specific body cavity. Endoscopes with integral working channels, or those characterised as resectoscopes, are generally employed when the body cavity may be accessed through a natural body opening - such as the cervical canal to access the endometrial cavity of the uterus, or the urethra to access the prostate gland and the bladder. Endoscopes specifically designed for use in the endometrial cavity are referred to as hysteroscopes, and those designed for use in the urinary tract include cystoscopes, urethroscopes and resectoscopes. The procedures of transurethal resection or vaporisation of the prostate gland are known as TURP and EVAP respectively. When there is no natural body

opening through which an endoscope may be passed, the technique of triangulation is commonly employed. Triangulation is commonly used during underwater endoscopic surgery on joint cavities such as the knee and the shoulder. The endoscope used in these procedures is commonly referred to as an arthroscope.

Electrosurgery is usually carried out using either a monopolar instrument or a bipolar instrument. With monopolar electrosurgery, an active electrode is used in the operating region, and a conductive return plate is secured to the patient's skin. With this arrangement, current passes from the active electrode through the patient's tissues to the external return plate. Since the patient represents a significant portion of the circuit, input power levels have to be high (typically 150 to 250 watts), to compensate for the resistive current limiting of the patient's tissues and, in the case of underwater electrosurgery, power losses due to the fluid medium which is rendered partially conductive by the presence of blood or other body fluids. Using high power with a monopolar arrangement is also hazardous, due to the tissue heating that occurs at the return plate, which can cause severe skin burns. There is also the risk of capacitive coupling between the instrument and patient tissues at the entry point into the body cavity.

With bipolar electrosurgery, a pair of electrodes (an active electrode and a return electrode) are used together at the tissue application site. This arrangement has advantages from the safety standpoint, due to the relative proximity of the two electrodes so that radio frequency currents are limited to the region between the electrodes. However, the depth of effect is directly related to the distance between the two electrodes; and, in applications requiring very small electrodes, the inter-electrode spacing becomes very small, thereby limiting tissue effect and the output power. Spacing the electrodes further apart would often obscure vision of the application site, and would require a modification in surgical technique to ensure direct contact of both electrodes with the tissue.

There are a number of variations to the basic design of the bipolar probe. For example, U.S. Patent Specification No. 4706667 describes one of the fundamentals of the design, namely that the ratio of the contact areas of the return electrode and of the active electrode is greater than 7:1 and smaller than 20:1 for cutting purposes. This range relates only to cutting electrode configurations. When a bipolar instrument is used for desiccation or coagulation, the ratio of the contact areas of the two electrodes may be reduced to approximately 1:1 to avoid differential electrical stresses occurring at the contact between the tissue and the electrode.

The electrical junction between the return electrode and tissue can be supported by wetting of the tissue by a conductive solution such as normal saline. This ensures that the surgical effect is limited to the active electrode, with the electric circuit between the two electrodes being completed by the tissue. One of the obvious limitations with the design is that the active electrode (typically a needle) must be completely buried in the tissue to enable the return electrode to complete the circuit. Another problem is one of the orientation: even a relatively small change in application angle from the ideal perpendicular contact with respect to the tissue surface, will change the contact area ratio, so that a surgical effect can occur in the tissue in contact with the return electrode.

Cavity distension provides space for gaining access to the operation site, to improve visualisation, and to allow for manipulation of instruments. In low volume body cavities, particularly where it is desirable to distend the cavity under higher pressure, liquid rather than gas is more commonly used due to better optical characteristics, and because it washes blood away from the operative site.

Conventional underwater electrosurgery has been performed using a non-conductive liquid (such as 1.5% glycine) as an irrigant, or as a distension medium to eliminate electrical conduction losses. Glycine is used in isotonic concentrations to prevent osmotic changes in the blood when intra-vascular absorption occurs. In the course of an operation, veins may be severed, with resultant infusion of the liquid into the

circulation, which could cause, among other things, a dilution of serum sodium which can lead to a condition known as water intoxication.

The applicants have found that it is possible to use a conductive liquid medium, such as normal saline, in underwater endoscopic electrosurgery in place of non-conductive, electrolyte-free solutions. Normal saline is the preferred distension medium in underwater endoscopic surgery when electrosurgery is not contemplated, or a non-electrical tissue effect such as laser treatment is being used. Although normal saline (0.9%w/v; 150mmol/l) has an electrical conductivity somewhat greater than that of most body tissue, it has the advantage that displacement by absorption or extravasation from the operative site produces little physiological effect, and the so-called water intoxication effects of non-conductive, electrolyte-free solutions are avoided.

Carbon dioxide is the preferred gaseous distension medium, primarily because of its non-toxic nature and high water solubility.

The applicants have developed a bipolar instrument suitable for underwater electrosurgery using a conductive liquid or gaseous medium. This electrosurgical instrument for the treatment of tissue in the presence of a fluid medium, comprises an instrument body having a handpiece and an instrument shaft and an electrode assembly, at one end of the shaft. The electrode assembly comprises a tissue treatment (active) electrode which is exposed at the extreme distal end of the instrument, and a return electrode which is electrically insulated from the tissue treatment electrode and has a fluid contact surface spaced proximally from the exposed part of the tissue treatment electrode. In use of the instrument, the tissue treatment electrode is applied to the tissue to be treated whilst the return electrode, being spaced proximally from the exposed part of the tissue treatment electrode, is normally spaced from the tissue and serves to complete an electrosurgical current loop from the tissue treatment electrode through the tissue and the fluid medium. This electrosurgical instrument is described in the specification of our International Patent Application No. PCT/GB96/01473.

The electrode structure of this instrument, in combination with an electrically-conductive fluid medium largely avoids the problems experienced with monopolar or bipolar electrosurgery. In particular, input power levels are much lower than those generally necessary with a monopolar arrangement (typically 100 watts). Moreover, because of the relatively large spacing between its electrodes, an improved depth of effect is obtained compared with conventional bipolar arrangements.

The specification of our International Patent Application No. GB96/01472 describes an irrigated bipolar electrosurgical instrument that can be used in open air or gas-filled environments. This instrument includes an internal channel for feeding electrically-conductive fluid (typically saline) to the exposed end of a tissue treatment electrode so as to provide a conductive fluid path that completes an electrical circuit to a return electrode when the instrument is in use. This instrument also includes an internal channel for removing fluid from the region of the exposed end of the tissue treatment electrode. When the fluid is a liquid, such as saline, the presence of that liquid can cause collateral tissue damage, so its removal is desirable. This type of instrument is intended primarily for use in open air or gas-filled environments, and is not suitable for use with electrosurgical procedures which require distension of a body cavity.

However, where the volume of a body cavity is small - for example in arthroscopic surgery where even the large joints, such as the knee, may only accommodate 50-60 ml of irrigation fluid - the following problems may occur, namely:-

(i) Heated fluid in the immediate vicinity of the tissue contact electrode can cause collateral tissue damage;

(ii) The products of the tissue vaporised by the tissue contact electrode can cause visualisation problems; and

(iii) Soft tissue present in a joint space tends to move about, making it difficult to apply the active electrode to vaporise such tissue.

An arthroscope electrode may be characterised as short (100 to 140 mm), and rigid with a working diameter up to 5 mm. It can be introduced through a stab incision into a joint cavity (with or without a cannula) using the triangulation technique. Such an electrode is operated with a motion which moves the electrode between the 9 0'Clock and 3 0'Clock positions on the arthroscopic image. As a result, the tissue to be treated is usually approached at a shallow working angle with respect to the axis of the electrode. An arthroscopic electrode thus needs to have an effect consistent with this angled approach to the tissue. The tissue to be treated, such as meniscal cartilage, is commonly dense and of a high electrical impedance. An arthroscope electrode requires output power and voltage settings that reflect the type of tissue being treated, the size of electrode, and the fact that arthroscopists are seeking a speed of effect comparable to that of the mechanical shaver devices they currently employ, albeit with an electrode of smaller dimensions than a shaver blade for improved access.

The specification of our British Patent Application 9612993.7 describes an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium. The instrument comprises an instrument shaft, and an electrode assembly at one end of the shaft, the electrode assembly comprising a tissue treatment electrode and a return electrode which is electrically insulated from the tissue treatment electrode by means of an insulation member. The tissue treatment electrode has an exposed end for treating tissue, and the return electrode has a fluid contact surface which is spaced from the tissue treatment electrode in such a manner as to define, in use, a conductive fluid path that completes an electrical circuit between the tissue treatment electrode and the return electrode. The electrode assembly is provided with a plurality of apertures in the region of the tissue treatment electrode, through which apertures vapour bubbles and/or particulate material can be aspirated from the region surrounding the tissue treatment electrode.

An RF generator is provided for powering the electrode assembly. The power required from the RF generator to achieve vaporisation depends on a number of variables more fully described in the specification of our International Patent Application No.

GB97/00065. Of these variables two, are of particular importance in the context of the present invention: one being the cooling effect produced by the aspiration of conductive fluid in the region of the tissue contact electrode, and the other being the disruption of the vapour pocket formed around the tissue contact electrode by the flow of conductive fluid. These problems can be partially overcome by co-ordinating the aspiration by monitoring the output features of the generator which indicate the vaporisation power threshold has been exceeded. This usually results in a series of suction pulses as the vaporisation threshold is repeatedly exceeded between pulses and then elevated during the suction pulses so that, should vaporisation be maintained, the suction will be applied continuously. By using this technique, heated saline in the vicinity of the tissue contact electrode and vaporisation products can be successfully removed. The other desirable feature is the aspiration of loose tissue towards the tissue contact electrode, so that it can be stabilised during vaporisation. Whilst this can be achieved according to this technique: there are two significant performance limitations.

The first of these limitations is that the gaseous products of tissue vaporisation contain fatty products which have a sublimation property, i.e. they condense directly to a solid; sublimation occurring at temperatures well above boiling point. As the electrode shaft within the body cavity is cooled by the surrounding saline, these products are easily condensed. Thus, if a parallel suction shaft is used, the build up is along its entire length, and eventually completely blocks the tube. This process, even at the flow rates dictated by minimal influence on the power threshold, can cause very rapid blocking. For example, it is found that, with a moderately large electrode tip, using a 1mm internal diameter suction tube, complete blockage occurs after 30 seconds of activation. Obviously, a larger tube bore would increase the time before blockage, but this occurs so rapidly that the required bore size for a useful electrode life is beyond the dimensions of the maximum shaft diameter. The problems of sublimation are compounded by aspiration of tissue pieces which are incompletely vaporised before being excised from the remainder of the tissue. Given the need to attract tissue and, therefore, the requirement for a strong suction pressure which, once tissue is engaged with the tissue contact electrode and the vaporisation threshold is continually exceeded by cessation of

flow, increases the propensity for aspiration of unvaporised tissue and blockage of the aspiration channel.

The second of these limitations also relates to adherence of tissue to the tissue contact electrode. As indicated above, once the tissue obstructs flow, the vaporisation power threshold is exceeded, and suction is continuously applied. Under these circumstances, and particularly when aspiration channels are provided adjacent to the tissue treatment electrode, a steady state can be reached wherein the tissue is held around the periphery of the tissue contact electrode, the portion of tissue in the immediate vicinity of the tissue treatment electrode is vaporised but, without moving the application site or redirecting suction solely through the tissue treatment electrode, no further removal of tissue will occur. For example, large pieces of tissue tend to bridge the tissue treatment electrode, so that all tissue in contact with the electrode is removed, but the bulk of the tissue is left in place. Applying suction solely through the tissue treatment electrode limits the size of the electrode otherwise two extremes are created where, on the one hand during activation in conductive fluid, the vaporisation power threshold is very elevated despite synchronising suction pulses with the RF output, typically >200 Watts, yet, on the other hand, can be reduced to below 50% of this level once tissue is engaged. With a static tissue contact electrode, there is an inevitable compromise between these performances variables.

The aim of the invention to provide an improved electrosurgical instrument of this type.

The present invention provides an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the instrument comprising an instrument shaft, a tissue treatment electrode mounted at one end of the shaft, and removal means, the instrument having an apertured portion through which matter can be aspirated by the removal means from the region surrounding the tissue treatment electrode, the removal means comprising a channel formed within the instrument shaft and leading from the apertured portion, wherein the channel is provided with agitation means movable relative thereto.

The agitation means thus prevents the build-up of sublimation products within the channel.

Advantageously, the instrument further comprises a return electrode which is electrically insulated from the tissue treatment electrode by insulation means, the tissue treatment electrode being exposed at the distal end of the instrument, and the return electrode having a fluid contact surface spaced proximally from the exposed end of the tissue treatment electrode.

Preferably, the channel is defined by the instrument shaft, and the agitation means is constituted by a rod mounted within, and movable relative to, the instrument shaft.

Conveniently, the tissue treatment electrode is constituted by the distal end portion of the rod. Thus, movement of the rod results in movement of the tissue treatment electrode, and this prevents tissue bridging, as the tendency for tissue to obstruct the channel is obviated by the electrode movement ensuring that such tissue is treated. Tissue can, therefore, be electrosurgically removed from an operation site by a vaporisation technique, and can be electrosurgically morcellated (that is to say chewed up) in this region by the moving tissue treatment electrode, this process being analogous to a miniature liquidiser.

Advantageously, the rod is constituted by a tungsten wire having a diameter in the range of from 0.2mm to 1.0mm. Preferably, the tungsten wire has a diameter in the range of from 0.4mm to 0.6mm.

Advantageously, the tissue treatment electrode is angled with respect to the longitudinal axis of the instrument shaft, and the instrument further comprises an insulating sleeve surrounding the rod proximally of said angled end portion. The insulating sleeve may be a ceramic sleeve.

Preferably, the instrument further comprises an insulation member provided at the distal end of the instrument shaft, the insulation member defining said apertured region. The insulation member may be made of a ceramic material.

Advantageously, the insulation member is formed with a slot which constitutes the apertured region, the tissue treatment electrode passing through the slot. Alternatively, the apertured region is constituted by a gap between the tissue treatment electrode and the insulation member.

In a preferred embodiment, the instrument further comprises drive means for reciprocating the rod within the channel. Advantageously, the drive means is constituted by a motor and coupling means for converting the rotary output of the motor into reciprocatory movement of the rod.

In this case, the angled end portion of the rod may be at right-angles to the longitudinal axis of the instrument shaft, and the tip of the angled end portion may constitute the tissue contacting portion of the tissue treatment electrode. This electrode is, therefore, a side effect electrode.

In another preferred embodiment, the instrument further comprises drive means for rotating the rod within the channel. An electric motor may constitute the drive means.

In this case, the drive rod may be formed with a portion off-set from the longitudinal axis of the instrument shaft.

Advantageously, the angled end portion of the rod is at right-angles to the longitudinal axis of the instrument shaft, and the distal end surface of said angled end portion constitutes the tissue contacting portion of the tissue treatment electrode. The rotation of the angled end portion of the rod permits the use of a small diameter rod, and hence the use of a small tissue treatment electrode, whilst providing a relatively large area

tissue contacting position. The use of a small diameter tissue treatment electrode also permits the use of lower electrosurgical powers and/or higher fluid medium flow rates.

Alternatively, the angled end portion of the rod makes an acute angle with the longitudinal axis of the instrument shaft, and the insulation member is provided with an inclined cam surface which is engagable with the apex of the angled end portion of the rod.

It is also possible for the angled end portion of the rod to be bent back around the distal end portion of the insulating sleeve.

Preferably, the removal means further comprises a pump connected to the channel at a region thereof remote from the apertured portion of the instrument. The pump may be activated cyclically whereby matter is aspirated by the removal means in a pulsed fashion. Conveniently, the pump is activated only when the tissue treatment electrode is powered for tissue vaporisation.

The instrument may further comprise an RF generator having a bipolar output connected to the tissue treatment electrode and the return electrode. Preferably, the pump is controlled in dependence upon the output characteristics of the RF generator.

The electrosurgical instrument of the invention is useful for dissection, resection, vaporisation, desiccation and coagulation of tissue, as well as for combinations of these functions. It has a particular application in arthroscopic surgery as it pertains to endoscopic and percutaneous procedures performed on joints of the body including, but not limited to, such techniques as they apply to the spine and other non-synovial joints. Arthroscopic operative procedures may include: partial or complete meniscectomy of the knee joint including meniscal cystectomy; lateral retinacular release of the knee joint; removal of anterior and posterior cruciate ligaments or remnants thereof; labral tear resection, acromioplasty, bursectomy and subacromial decompression of the shoulder joint; anterior release of the temperomandibular joint; synovectomy, cartilage

debridement, chondroplasty, division of intra-articular adhesions, fracture and tendon debridement as applied to any of the synovial joints of the body; inducing thermal shrinkage of joint capsules as a treatment for recurrent dislocation, subluxation or repetitive stress injury to any articulated joint of the body; discectomy either in the treatment of a disc prolapse or as part of a spinal fusion via a posterior or anterior approach to the cervical, thoracic and lumbar spine or any other fibrous joint for similar purposes; excision of diseased tissue; and haemostasis.

The instrument of the invention is also useful for dissection, resection, vaporisation, desiccation and coagulation of tissue, as well as combinations of these functions, with particular application in urological endoscopic (urethroscopy, cystoscopy, ureteroscopy and nephroscopy) and percutaneous surgery. Urological procedures may include: electro-vaporisation of the prostate gland (EVAP) and other variants of the procedure commonly referred to as transurethral resection of the prostate (TURP) including, but not limited to, interstitial ablation of the prostate gland by a percutaneous or perurethral route whether performed for benign or malignant disease; transurethral or percutaneous resection of urinary tract tumours as they may arise as primary or secondary neoplasms, and further as they may arise anywhere in the urological tract from the calyces of the kidney to the external urethral meatus; division of strictures as they may arise at the pelviureteric junction (PUJ), ureter, ureteral orifice, bladder neck or urethra; correction of ureterocoele; shrinkage of bladder diverticular; cystoplasty procedures as they pertain to corrections of voiding dysfunction; thermally induced shrinkage of the pelvic floor as a corrective treatment for bladder neck descent; excision of diseased tissue; and haemostasis.

The electrosurgical instrument of the invention is also useful for dissection, resection, vaporisation, desiccation and coagulation of tissue and combinations of these functions with particular application in laparascopic, colposcopic (including vaginal speculum) and open surgical procedures on the female genital tract and adnexal related diseases. Laparascopic operative procedures may include: removal of subserosal and pedunculated fibroids, ablation of ectopic endometrium, ovarian cystectomy and ovarian drilling

procedures; oophorectomy, salpingo-oophorectomy, subtotal hysterectomy and laparaoscopically assisted vaginal hysterectomy (LAVH) as may be performed for benign or malignant diseases; laparoscopic uterosacral nerve ablation (LUNA); fallopian tube surgery as correction of ectopic pregnancy or complications arising from acquired obstructions; division of abdominal adhesions; and haemostasis.

The electrosurgical instrument of the invention is also useful in the lower female genital tract, including treatment of cervix, vagina and external genitalia whether accessed directly or using instrumentation comprising generally speculae and colposcopes. Such applications include: vaginal hysterectomy and other pelvic procedures utilising vaginal access; LLETZ/LEEP procedure (large loop excision of the transformation zone) or excision of the transformation zone of the endocervix; removal of cystic or septic lesions; ablation of genital or venereal warts; excision of benign and malignant lesions; cosmetic and surgical repairs including vaginal prolapse; excision of diseased tissue; and haemostasis.

The electrosurgical instrument of the invention is also useful for dissection, resection, vaporisation, desiccation and coagulation of tissue and combinations of these functions with particular application in surgery on the ear, nose and throat (ENT), and more particularly procedures performed on the oropharynx, nasopharynx and sinuses. These procedures may be performed through the mouth or nose using speculae or gags or using endoscopic techniques such as functional endoscopic sinus surgery (FESS). Functional endoscopic sinus procedures may include: removal of chronically-diseased inflamed and hypertrophic mucus linings, polyps and neoplasms from the various anatomical sinuses of the skull; excision of diseased tissue; and haemostasis. Procedures on the nasopharynx may include: removal of chronically-diseased inflamed and hypertrophic mucus linings, polyps and neoplasms from the turbinates and nasal passages; submucous resection of the nasal septum; excision of diseased tissue; and haemostasis. Procedures on the oropharynx may include: removal of chronically-diseased, inflamed and hypertrophic tissue, polyps and neoplasms particularly as they occur related to the tonsil, adenoid, epi-glottic and supra-glottic regions, and salivary

glands; as an alternative method to perform the procedure commonly known as laser assisted uvolopalatoplasty (LAUP); excision of diseased tissue; and haemostasis.

It is evident from the scope of applications of the invention that it has further additional applications for dissection, resection, vaporisation, desiccation and coagulation of tissue and combinations of these functions in general laparoscopic, thoracscopic and neurosurgical procedures, being particularly useful in the removal of diseased tissue and neoplastic disease whether benign or malignant.

Surgical procedures using the electrosurgical instrument of the invention may also include introducing the electrode assembly to the surgical site, whether through an artificial conduit (a cannula) or a natural conduit, which may be in an anatomical body cavity or space, or one created surgically. The cavity or space may be distended during the procedure using a fluid, or may be naturally held open by anatomical structures. The surgical site may be bathed in a continuous flow of conductive fluid such as saline solution either to fill and distend the cavity, or to create a locally-irrigated environment around the tip of the electrode assembly in a gas filled cavity. The irrigating fluid may be aspirated from the surgical site to remove products created by application of the RF energy, tissue debris or blood. The procedures may include simultaneous viewing of the site via an endoscope, or using an indirect visualisation means. An irrigated bipolar electrosurgical instrument is described in the specification of our International Patent Application No. PCT/GB96/01472.

The invention will now be described in greater detail, by way of example with reference to the drawings, in which:-

Figure 1 is a diagram showing an electrosurgical apparatus constructed in accordance with the invention;

Figure 2 is a diagrammatic side elevation, partially broken away, of a first form of electrode unit constructed in accordance with the invention;

Figure 3 is a diagrammatic side elevation of the electrode assembly of the electrode unit of Figure 2;

Figure 4 is a diagrammatic side elevation, partially broken away, of a second form of electrode unit constructed in accordance with the invention;

Figure 5 is a diagrammatic side elevation of the electrode assembly of the electrode unit of Figure 4;

Figure 6 is a diagrammatic side elevation, partially broken away, of a third form of electrode unit constructed in accordance with the invention;

Figure 7 is a diagrammatic side elevation of the electrode assembly of the electrode unit of Figure 6;

Figure 8 is a diagrammatic side elevation, partially broken away, of a fourth form of electrode unit constructed in accordance with the invention; and

Figure 9 is a diagrammatic side elevation of the electrode assembly of the electrode unit of Figure 8.

Referring to the drawings, Figure 1 shows electrosurgical apparatus including a generator 1 having an output socket 2 providing a radio frequency (RF) output, via a connection cord 4, for an instrument in the form of a handpiece 3. Activation of the generator 1 may be performed from the handpiece 3 via a control connection (not shown) in the cord 4, or by means of a footswitch unit 5 connected separately to the rear of the generator 1 by a footswitch connection cord 6. In the illustrated embodiment, the footswitch unit 5 has two footswitches 5a and 5b for selecting a desiccation mode and a vaporisation mode of the generator 1 respectively. The generator front panel has push buttons 7a and 7b for respectively setting desiccation and vaporisation power levels, which are indicated in a display 8. Push buttons 9 are provided as an alternative means for selection between the desiccation and vaporisation modes.

The handpiece 3 mounts a detachable electrode unit E, such as the electrode units E1 and E4 to be described below.

Figure 2 shows the first form of electrode unit E1 for detachable fastening to the electrosurgical instrument handpiece 3, the electrode unit comprising a shaft 10, which

The provision of the suction pump ensures the elimination of vapour bubbles from an operation site, which is particularly advantageous during aggressive tissue debulking. The suction pump is activated only when the active electrode 12 is powered for tissue vaporisation. The pump is, therefore, pulsed so as to pull saline over the active electrode 12 (and to extract vapour bubbles and/or particulate material). This cools the active electrode 12, resulting in the collapse of the vapour pocket surrounding the active electrode. This, in turn, leads to the suction pump being turned off, thereby reducing the flow of saline over the active electrode 12. This electrode 12 then heats up again, leading to the re-formation of a vapour pocket, and the re-activation of the suction pump. This cycle then repeats until the generator 1 is turned off when the instrument is removed from the operation site.

The suction pump must be controlled so that the flow of bubbles from the active electrode 12 is balanced to the output characteristics of the RF generator 1 to prevent excessive cooling of the active electrode and a resultant increase in its vaporisation power threshold. The thermal mass of the thin, wire-form active electrode 12 is lower than that of a standard solid form active electrode, and this assists in rapidly re-establishing the vapour pocket around the active electrode should this collapse following excessive cooling.

The electrode unit E1 is intended primarily for use in arthroscopic surgery which requires rapid tissue debulking by vaporisation. The side-effect electrode (i.e. where the treatment axis is perpendicular to the shaft) configuration of the unit E1 is particularly advantageous for this purpose. In use, the electrosurgical instrument is manipulated to introduce the electrode assembly constituted by the active electrode 12 and the return electrode 28 into a selected operation site (e.g. within the joint space of a knee), so that the active electrode contacts the tissue to be treated, and the tissue and the electrode assembly are immersed in saline.

The footswitch 5b (or the push button 7b) is then operated to activate the generator 1. The generator 1 then provides sufficient RF power to the electrode assembly to vaporise

the saline surrounding the active electrode 12, and to maintain a vapour pocket surrounding this electrode. Using a brushing technique, with firm pressure against the tissue surface, rapid debulking of the tissue is achieved. Gently touching the tissue will reduce the effect, and can be used to sculpture and smooth the residual tissue surface. With tissue engagement, the flow of irrigant away from the active electrode 12 will be reduced, the amount of reduction depending on the nature of the tissue surface, the application pressure and the suction pressure. Speed of debulking will, therefore, depend on these variables. Once the vaporisation occurs, the products will include vapour bubbles, carbon particles and tissue debris. All of these products are removed from the region of the active electrode 12, via the shaft 10 and the port 10a, by the suction pump.

All the constituents removed from the active tip are at high temperatures. This could lead to a potentially dangerous heating of the electrode shaft 10, which could cause tissue damage at the entry point. It may be, therefore, necessary to aspirate additional coolant saline from the body cavity along the inside surface of the shaft. To ensure that this saline is indeed at a safe temperature, it is taken from the rear of the return electrode 28 via a mesh filter (not shown).

In use, when the generator 1 is turned on, the motor 44 begins to rotate, causing the rod 14 to oscillate with an amplitude of 0.5mm. The oscillation of the rod 14 within the shaft 10 provides a mechanical agitation within the shaft that is sufficient to dislodge any sublimation products which condense within the shaft. In this way, blockage of the shaft 10 is prevented, so that the instrument can be used on a continuous basis.

The oscillation of the active electrode 12 also ensures that tissue pieces removed electrosurgically by vaporisation from an operation side are morcellated electrosurgically by the oscillating electrode, thereby preventing large tissue pieces bridging the aspiration channel. Morcellation is the division of a tissue piece into many smaller pieces in order to facilitate its surgical removal.

The electrode unit E1 is also very effective in removing heated saline (distension fluid) from within a joint cavity. The risk of hot distension fluid occurs primarily during power application to reach the vaporisation threshold. Once the threshold has been reached, the power requirement falls by 30-50%.

Whilst aspiration from the region of the active electrode 12 will remove heated saline from the body cavity, and remove any risk of overheating through prolonged activation under conditions where the vaporisation threshold is not reached, the cooling effect and disruption of vapour pockets created around the active electrode will increase the vaporisation threshold. A vicious cycle can, therefore, be created, wherein the more suction applied at the active electrode 12, the more power required to reach the vaporisation threshold, and the greater the risk of heating. The other factor influencing the vaporisation threshold is the ratio of return: active contact area, and the insulation separation between the active electrode 12 and the return electrode 28. The size of the active electrode 12 and the insulation separation, must, therefore, be reduced to the minimum necessary to achieve the function in order to offset the effects of aspiration in elevating the power threshold of vaporisation.

The specification of our International Patent Application GB97/00065 discloses techniques for controlling the vaporisation threshold by employing active electrode designs which assist in capturing vapour pockets and preventing cooling of the active electrode application site by screening from the flow of irrigant provided by channels in an endoscope. An alternative method of reducing the vaporisation power threshold is to pulse the suction pressure, thereby allowing the threshold to be attained between pulses. Such pulses may be synchronised with the output features of the RF generator 1 to provide power bursts during active suction to sustain the vapour pocket, and clear any tissue occluding the apertures in the active electrode 12.

A known technique in arthroscopic surgery is to apply suction through a mechanical, tissue-nibbling device so that soft tissue present in the joint space, such as the

infrapatellar fat pad, can be held in position within the nibbler jaws by suction whilst it is progressively "nibbled away".

Attracting tissue to the active electrode 12 of the electrode unit E1 has a similar effect as, for the reasons already given above, compliant tissue adhering to the active electrode will result in a reduction of the vaporisation power threshold. Adherent tissue will be rapidly vaporised, and small tissue particles produced during vaporisation will be aspirated from the application site.

Because of its speed of debulking and side-effect configuration, the electrode unit E1 also has advantages in urological surgery as an EVAP technique for use in conjunction with a resectoscope. A resectoscope electrode unit is introduced very differently, in that is mounted on an endoscope prior to passage of the assembled instrument through a working sheath via the urethra. The proximal end of the electrode unit is connected to a trigger assembly and an electrical contact which is integral with the resectoscope. By this means, the electrode unit E1 can be moved back and forth through a defined range of motion by operating the trigger mechanism. As the electrode unit E1 is assembled prior to introduction, the size of the tip is not constrained by working channel dimensions, but rather by the diameter of the working sheath which can be up to 10 mm. Part of this diameter is occupied by the support wires to the electrode unit E1, which wires are commonly bent in a downward angle, with respect to the endoscopic image, to the working tip, so that they do not interfere with either visulation or its operation. Because of the reciprocatory movement of the rod 14, the active electrode 12 operates over a length lying within the range of from 3 mm to 4 mm and a width lying in the range of from 2 mm to 3 mm, and this size is necessary for urological surgery given that, on average, 20-30 grammes of prostate tissue must be removed.

Because of the reservoir effect of the urinary bladder, and the mounting of the endoscope to view the tip of the active electrode 12 from below, bubble generation during vaporisation is less of a problem during endoscopic urology, as the bubbles flow

away from the endoscope to accumulate in the bladder. Nevertheless, the use of the electrode unit E1 substantially reduces the possibility of bubble generation causing problems.

Although the electrode unit E1 is intended primarily for use in the vaporisation of tissue it can also be used for desiccation, particularly of synovial membranes or to separate muscle attachments. In this case, once the electrode assembly of the electrode unit E1 has been introduced into a selected operation site, the RF generator 1 is actuated using the footswitch 5a or the push button 7a. The generator 1 will then provide sufficient RF power to the electrode assembly to maintain the saline adjacent to the active electrode 12 substantially at its boiling point without creating a vapour pocket surrounding that electrode. The instrument can then be manipulated by moving the active electrode 12 across the surface of the tissue to be treated in a side-to-side "painting" technique.

The electrode unit E1 can also be used for delivering a blended power output. This is achieved by automatically alternating the output of the RF generator 1 between the desiccation and vaporisation power levels, more haemostasis being produced then is possible in the vaporisation mode. As a consequence, the speed of tissue debulking is reduced, but the increased haemostasis is useful when cutting or debulking vascular tissue structures. Alternatively, the output of the RF generator 1 can be pulsed at the vaporisation power level, without cycled activation of the desiccation mode. This produces a less aggressive tissue vaporisation than occurs in the vaporisation mode, with a consequent reduction in both bubble formation and the risk of tissue charring.

The active electrode 12 of the unit E1 is a side effect electrode (i.e. its treatment axis is perpendicular to the shaft). Axial agitation is advantageous with such electrodes, in that the entire electrode can be brought into contact with tissue. As a result, the exposed area can be made very small, allowing operation at lower powers and less at higher saline flow rates.

Figures 4 and 5 show the second form of electrode unit E2. This instrument is a modification of that shown in Figures 2 and 3, and so like reference numerals will be used for like parts, and only the modifications will be described in detail. There are two main modifications, the first being to the drive to the rod 14, and the second to the configuration of the active electrode 12.

In the first modification, the motor 44 rotatably drives the rod 14 via a coupling assembly 42. As with the embodiment of Figures 2 and 3, the rod 14 passes through aligned apertures in the washer 34, the gland 36 and the delrin bush 38. The bush 38 is somewhat longer than the equivalent bush of the embodiment of Figures 2 and 3 extending to the end 32a of the sleeve 32. A slip ring 46a is provided to connect the connector 46 to the rod 14.

The other main modification is that the active electrode 12 (the free end of the tungsten rod 14 - in this embodiment of 0.5mm diameter) is bent back over the free end of the ceramic tube 18. The turned-back portion 12a of the electrode 12 constitutes a side effect electrode. An apertured region 20a is formed between the ceramic tip 20 and the active electrode 12, this region loading to the aspiration channel defined by the interior of the shaft 10.

Another modification is that the rod 14 is a flexible drive rod whose distal end portion is off-set with respect to the central longitudinal axis of the shaft 10. In use, when the generator 1 is turned on, the motor 44 begins to rotate, causing the rod 14 to rotate within the shaft 10. This rotation provides a mechanical agitation that is sufficient to dislodge any sublimation products which condense within the shaft. The off-set of the rod 14 results in an unstable oscillation being set up in the rod, which sweeps adherent tissue debris from the inner wall of the shaft 10.

Figures 6 and 7 show the third form of electrode unit E3. This unit E3 is a modification of the unit E2, so like reference numerals will be used for like parts, and only the modifications will be described in detail. The main modification is to the